



NIEHS

National Institute of
Environmental Health Sciences

NAEHS Council: “Intramural Clinical Research Program”

February 16, 2006

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U.S. Department of Health and Human Services
National Institute of Health
National Institute of Environmental Health Sciences

Program in Clinical Research



- **Office of Clinical Research**
- **Program Investigators**
- **Future Directions**

Office of Clinical Research

Functions

- Advise Director, Scientific Director, and colleagues on clinical research
- Represent NIEHS clinical research at NIH
- Provide oversight and review functions and staffing for the NIEHS IRB
- Coordinate clinical research training programs at NIEHS
 1. Third year medical student program
 2. NIH-Duke training program in clinical research
 3. NIH Bench to Bedside program (2 awarded this year)
- Support Clinical Research Seminar Series
- Develop mechanisms to support clinical research at NIEHS
- Develop strategic plan for clinical research at NIEHS that is fully integrated into the plan for DIR and the NIEHS as a whole

Program in Clinical Research

Program Investigators

- Darryl C. Zeldin, MD (LRB)
- Frederick W. Miller, MD, PhD
- Perry J. Blackshear, MD, DPhil (LN)
- David A. Schwartz, MD (LRB)
- William J. Martin, MD (LRB) – new recruit
- Michael B. Fessler, MD (LRB) – new recruit
- Recruitment underway for clinical neuroscientist
- Next proposed topic for recruitment: Reproductive endocrinology

Current status

- Active collaborations ongoing between all possible pairs of Zeldin, Miller, Blackshear; and between Blackshear and Schwartz
- Currently responsible for 23 of 61 IRB-approved protocols in DIR
- Bi-weekly seminar series with videoconferencing ensuring active Bethesda participation
- Pending construction of the temporary Clinical Research Unit (CRU)

Proposed model for the PCR

- **Recruit one to two clinically oriented investigators each year until a steady state of 6-10 investigators is reached**
- **Topics will be chosen based on relevance to NIEHS mission and current DIR needs and interests; no attempt to focus on a single condition or group of related conditions**
- **In general, recruitments will be conducted jointly by the PCR and the relevant lab and branch chiefs**
- **Clinical studies will be conducted, when possible, in a new temporary Clinical Research Unit (CRU) located on the NIEHS campus**
- **Clinical studies requiring other locations will be conducted under a recently awarded clinical services contract (Constella)**
- **The Environmental Autoimmunity Group (EAG) in Bethesda, under the direction of Dr. Fred Miller, will continue to provide access for NIEHS investigators to the patients and infrastructure of the NIH Clinical Research Center (CRC)**

Training

- Regular pre and post graduate training programs
- Clinical research seminar series – alternating talks by fellows and outside speakers
- NIH-Duke Program in Clinical Research, leading to a Master's Degree in Clinical Research (sponsored by DIR; coordinated by Bill Schrader)
- Third year medical student training program (sponsored by DIR; coordinated by Bill Schrader)
- Memberships in local university fellowship training programs (e.g., endocrine, GI, pulmonary)
- Memberships in local university graduate programs

Temporary Clinical Research Unit (CRU)

- **Modular building of about 9,000 net usable square feet, located within walking distance of Building 101**
- **On-site location to maximize interactions and synergies between DIR investigators**
- **Will provide infrastructure and staffing for DIR clinical studies, with capability for subject histories, physical examinations, and biological sampling and sample preparation**
- **Facilities available for blood fraction preparation, cell culture, bronchoscopy, inhalation chamber exposures, pulmonary function tests**
- **Inpatients, more sophisticated imaging are planned for future permanent facility**

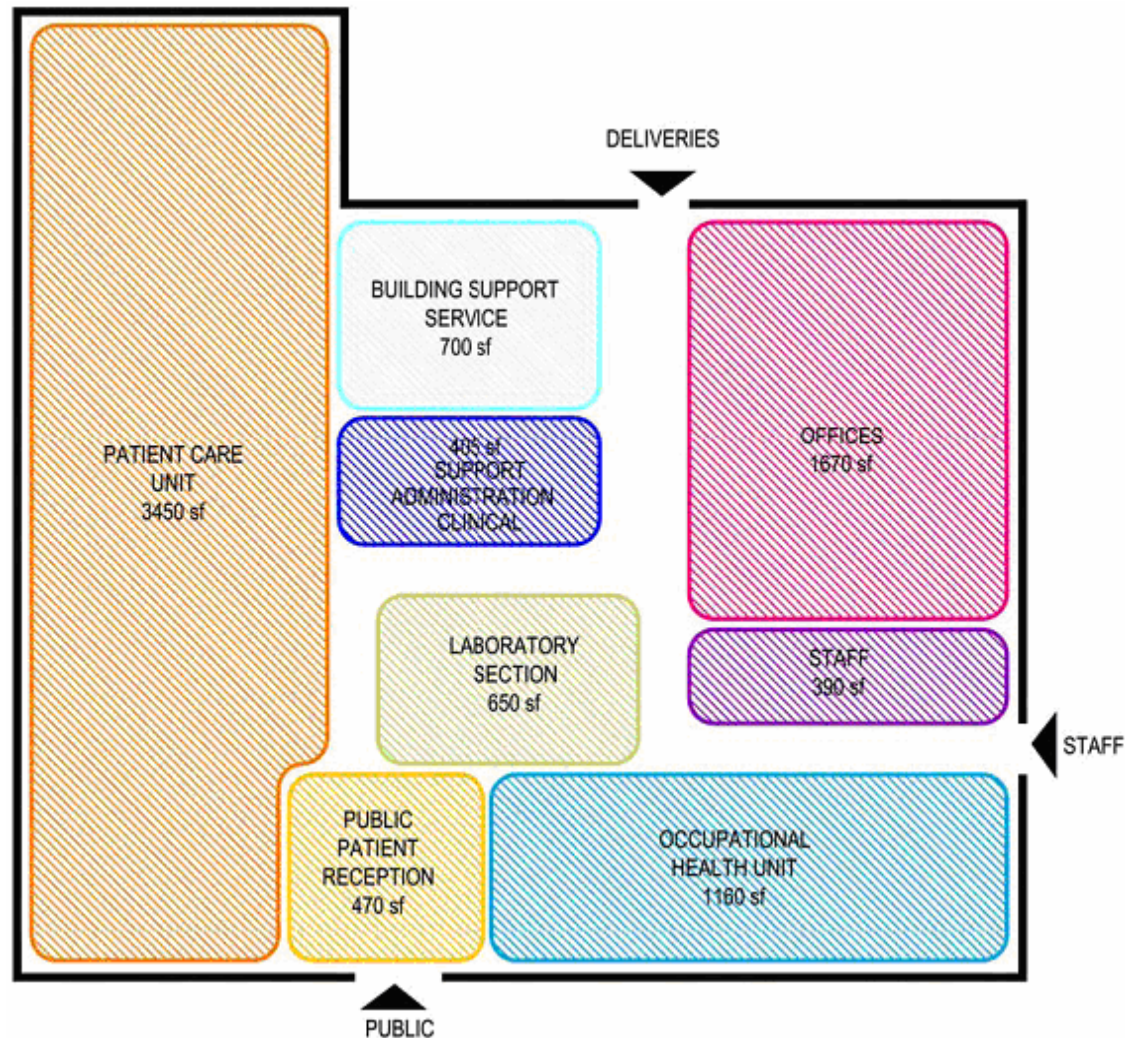
The site plan illustrates the layout of the CRU site. Key features include:

- CRU site:** Indicated by an arrow pointing to a building complex in the upper left.
- Lots:** Labeled Lot "A" through Lot "H".
- Lanes:** North Park Lane, Nobel Lane, Research Lane, Journal Lane, South Park Lane, Lakeview Drive, Environmental Parkway, T.W. Alexander Drive, Warehouse Alley, Power Alley, Facilities Lane, and Hopson Drive.
- Buildings:** Labeled A through F, and numbered 101 through 105.
- Other Features:** A large body of water (LAW) is shown in the upper right. A north arrow is located in the bottom right corner.

Aerial Location Map of Site Proposed for the Temporary CRU



Spatial Relationship Diagram for the Temporary Clinical Research Unit



Proposal for a permanent Clinical Research Unit in RTP

- **Second bronchoscopy/procedure room**
- **In-patient space including nursing and support features (4 beds expandable to 8 beds)**
- **Improved diagnostic radiology suite and upgradable imaging**
- **Multi-purpose clinical conference and training rooms**
- **Administrative & common space**
- **Total projected size: 28,644 nasf**

Projected site of permanent CRU

